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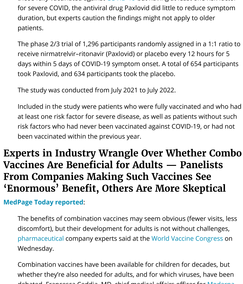
Among Fully Vaccinated, Study Shows Paxlovid Does Not Shorten Symptoms + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff



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Among Fully Vaccinated, Study Shows Paxlovid Does Not Shorten Symptoms

CIDRAP reported:

A new study in the New England Journal of Medicine suggests that, for those fully vaccinated against COVID-19 but having at least one risk factor for severe COVID, the antiviral drug Paxlovid did little to reduce symptom duration, but experts caution the findings might not apply to older patients.

The phase 2/3 trial of 1,296 participants randomly assigned in a 1:1 ratio to receive nirmatrelvir–ritonavir (Paxlovid) or placebo every 12 hours for 5 days within 5 days of COVID-19 symptom onset. A total of 654 participants took Paxlovid, and 634 participants took the placebo.

The study was conducted from July 2021 to July 2022.

Included in the study were patients who were fully vaccinated and who had at least one risk factor for severe disease, as well as patients without such risk factors who had never been vaccinated against COVID-19, or had not been vaccinated within the previous year.

Experts in Industry Wrangle Over Whether Combo Vaccines Are Beneficial for Adults — Panelists From Companies Making Such Vaccines See 'Enormous' Benefit, Others Are More Skeptical

MedPage Today reported:

The benefits of combination vaccines may seem obvious (fewer visits, less discomfort), but their development for adults is not without challenges, pharmaceutical company experts said at the World Vaccine Congress on Wednesday.

Combination vaccines have been available for children for decades, but whether they're also needed for adults, and for which ones, has been debated. Francesca Ceddia, MD, chief medical affairs officer for Moderna, said another perk of combined vaccines is the potential to increase coverage rates.

Ceddia also highlighted the potential to increase vaccine uptake for lesser-known illnesses — for example, by pairing vaccination for respiratory syncytial virus (RSV) with human metapneumovirus (HMPV).

The viruses also have matching seasonality and a similarly underestimated burden of disease, even more so for HMPV, she said. Moderna is working on such a vaccine and to date has completed phase I trials in pediatric populations.

Wider Bird Flu Spread Raises Concern for Humans, Animal Health Body Says

Reuters reported:

The spread of bird flu to an increasing number of species and its widening geographic reach have raised the risks of humans being infected by the virus, the head of the World Organization for Animal Health (WOAH) said on Thursday.

Monique Eloit's comments come after the U.S. government reported cases of the disease in dairy cows in several states and a person in Texas, which she said would only be a strong concern if there had been a transmission between cows, something the U.S. authorities are still investigating.

"Over the last few months, we have had a whole series of these and varied mammals. It is worrying to see this extension to other species," the head of the Paris-based organization told Reuters in an interview. "Ultimately, we find ourselves with more and more species and more animals which are contaminated, therefore necessarily a higher viral load with a risk of contamination of humans," she said.

The European Food Safety Agency (EFSA) warned on Wednesday of a large-scale bird flu pandemic if the virus becomes transmissible between people as humans lack immunity against the virus.

Ozempic Side Effects Caused Gastritis, Gallbladder Injury and Uncontrollable Vomiting, Lawsuit Claims

AboutLawsuits.com reported:

A Texas woman says she had to have her gallbladder removed and suffered other severe gastrointestinal side effects from Ozempic, which she received as a prescription from her doctor to promote weight loss.

The complaint was filed by Miquana Renteria in the U.S. District Court for the Eastern District of Pennsylvania on March 26, indicating that Novo Nordisk failed to provide adequate warnings about the serious nature of Ozempic side effects for users or the medical community.

Although advertisements promote the drug as safe and effective, with few serious health risks, Renteria and a growing number of other former users are now pursuing Ozempic lawsuits and Wegovy lawsuits against Novo Nordisk, each raising similar allegations that a large number of users are experiencing long-term side effects, including gallbladder injuries, intestinal blockages, stomach paralysis and other injuries.

Yale Researchers Weigh in on New COVID Drug

Yale Daily News reported:

Pemgarda is a monoclonal antibody infusion, meaning that doctors administer lab-made clones of an antibody found in the immune system to the body via an IV tube. These proteins then act like the cloned antibody, defending the body against foreign invaders. The infusion, Gandhi said, maintains a protective antibody level for about three months, providing immunocompromised patients with the antibody for COVID-19 they can't produce on their own.

However, after those three months, antibody levels wane, and patients are again at risk for infection. Due to this dip in antibodies, the FDA declared that patients may receive Pemgarda infusions every three months.

SARS-CoV-2 is constantly evolving, and it continues to mutate and change the morphology of its spike protein. While antibodies can recognize these spike proteins and neutralize the virus, if the spike proteins change following a mutation, the virus can evade detection and enter cells.

For Gandhi, these high mutation rates have rendered previous monoclonal antibody treatments ineffective. Still, Pemgarda produces certain side effects, including redness and swelling at the infusion site, feelings of illness after the infusion and a risk of a severe — even life-threatening — allergic reaction.

Sanofi Pledges to Keep Polio Vaccine Supplies Afloat in India After New Approval

Fierce Pharma reported:

After press reports flagged the possibility of an inactivated polio vaccine (IPV) shortage in India, Sanofi says it's ready to supply the nation with a newly approved shot.

Thursday, after the company gained an approval for a new polio vaccine, IMOVAX-Polio, Sanofi issued an assurance that it will be able to keep providing sufficient supplies. The developments come quickly on the heels of an Economic Times report alleging that a shortage crisis was looming following Sanofi's decision to shut down certain vaccine manufacturing operations in the country.

Last September, Sanofi revealed plans to discontinue its previous polio shot in India.

Regarding the company's decision to discontinue its previous polio shot, Sanofi India's spokesperson pointed to the rapidly shifting healthcare environment in the country following the COVID-19 pandemic.

AstraZeneca's Imfinzi Improves Survival in Late-Stage Lung Cancer Trial

Reuters reported:

AstraZeneca (AZN.L) said on Friday its blockbuster cancer drug Imfinzi helped improve survival in patients in the early stages of an aggressive type of lung cancer, making it the first such immunotherapy to meet two key trial goals.

In a late-stage trial, the drug demonstrated "statistically significant and clinically meaningful improvement" in both overall survival and slowing the progression of cancer in patients for whom the disease had not worsened following chemoradiotherapy, according to the Anglo-Swedish drugmaker.

Imfinzi clocked $4.24 billion in sales in 2023 and is a blockbuster medicine in AstraZeneca's key oncology portfolio, which makes up more than 20% of its total revenues.

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